K093858

PREMARKET NOTIFICATION [510(K)] SUMMARY

APR - 2 2010

Date Prepared: March 30, 2010

Submitter: St. Jude Medical, CRMD
Address: 15900 Valley View Court
Sylmar, CA 91342
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Contact Person: Beena Flynn

Trade Name/Proprietary Name: PSA Cable Model Numbers 4160 and 4161
PSA Cable Adapter Model Number 4053A

Common Name: Disposable Surgical PSA cables
Non-Disposable PSA adapters

Classification: Class II, 21 CFR 870.3720
Class II, 21 CFR 870.2900

Legally marketed device to which your firm is claiming equivalence: St. Jude Medical PSA cables and adapters under review are all currently commercially available.

Model Number (Cables)	Equivalent Device	PMA Number	Approval Date
4160	4160	P910023 / S154, P030054 / S67, P950022 / S42	January 13, 2009
4161	4161	P910023 / S154, P030054 / S67, P950022 / S42	January 13, 2009

Model Number (Adaptor)	Equivalent Device	510(k) Number	Approval Date
4053A	Remington Medical cable adapter Model 4053	K971968	July 23, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

St. Jude Medical CRMD
c/o Ms. Beena Flynn
Regulatory Affairs
15900 Valley View Court
Sylmar, CA 91342

APR - 2 2010

Re: K093858
Trade/Device Name: PSA Cable Model Numbers 4160 and 4161
PSA Cable Adapter Model Number 4053A
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient transducer and electrode cable (including connector)
Regulatory Class: Class II (two)
Product Code: DSA and DTA
Dated: December 15, 2009
Received: December 16, 2009

Dear: Ms. Flynn

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Device Name: PSA Cable Model Numbers 4160 and 4161

Indications for Use: The Model 4160 PSA disposable threshold cable is intended to connect IS-1 or SJ4 leads to the Biotronik PK-67S PSA patient cable adapter and, in turn, to the SJM Model 3150 PSA or Biotronik Model ERA 300B PSA (Pacing System Analyzer) located outside the sterile field.

The Model 4161 PSA disposable threshold cable is intended to connect IS-1 or SJ4 leads to St. Jude Medical PSA patient cable adapter Models 4053 and 4053A and, in turn, to a testing device such as a PSA (Pacing System Analyzer) located outside the sterile field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093858

STATEMENT OF INDICATIONS FOR USE

Device Name: PSA Cable Adapter Model Number 4053A

Indications for Use: The Model 4053A non-disposable PSA cable adapter is intended to be used with the St. Jude Medical Model 4051 and 4051A cables to connect a cardiac pacing lead to the SJM Model 3150 PSA or Biotronik model ERA 300B PSA (Pacing System Analyzer) located outside the sterile field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)